












INSTRUCTIONS FOR USE

St. Jude Medical™

Stented Porcine Tissue Valves Epic™ / Epic™ Supra

SN	Serial Number		Temperature Limitation
	Use By Date		Manufacturing Date
REF	Model Number		Consult Instructions for Use
	Single Use Only		Manufacturer
	Processed Using Aseptic Technique		Authorized European Representative
	Sterilized by Liquid Chemical Sterilant		Do Not Use if Packaging is Damaged
681936-001 D			Do Not Re-Sterilize

DEVICE DESCRIPTION

The Epic™ valve (**Figure 1**) and the Epic™ Supra valve (**Figure 2**) are bioprosthetic heart valves manufactured from select porcine aortic valve cusps. The cusps are carefully matched for optimum leaflet coaptation and hemodynamics.

Following tissue fixation, the tissue is mounted on the FlexFit™ polyester-covered flexible acetal copolymer stent. The stent is a low-profile design with a scalloped shape.

The stent is covered with knitted polyester fabric. The sewing cuff on Epic standard valves is formed from a braided polyester filler material that is covered by the knitted polyester fabric cover. The sewing cuff on Epic Supra valves is formed by enclosing a molded silicone elastomer within the same knitted polyester fabric as the Epic standard valve. The sewing cuff also contains three suture markers to facilitate valve placement. A stainless steel wire is located under the sewing cuff for radiopacity.

A bovine pericardial tissue strip is attached to the outflow edge of the valve. This strip protects the leaflets as they open and close. The pericardial strip and the porcine valve cusps are preserved and crosslinked in a glutaraldehyde solution. Glutaraldehyde, formaldehyde, and ethanol are used in the valve sterilization

process. The valve is attached to a holder and packaged in a sealed jar containing a formaldehyde solution. The Epic and Epic Supra valves are supplied sterile and non-pyrogenic.

Non-clinical testing has demonstrated that the Epic and Epic Supra valves are MR Conditional. Refer to the MRI Safety Information section of this manual for further information.

The Epic valves are available in the aortic and mitral sizes indicated in Table 1. Epic standard valves are designed to allow intra-annular placement of the inflow edge of the valve with supra-annular placement of the sewing cuff.

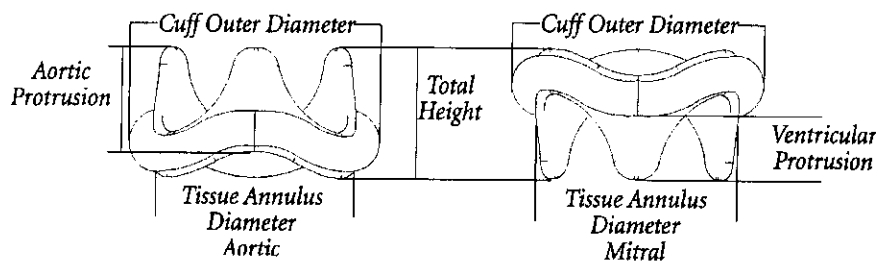


Figure 1: Epic Aortic and Epic Mitral Valves

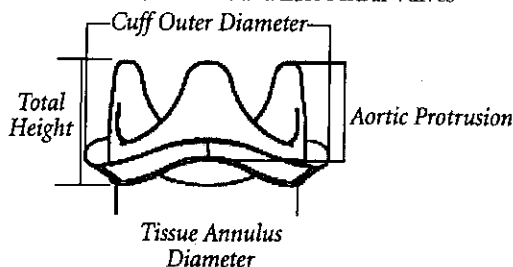


Figure 2: Epic Supra Aortic Valve

Epic Supra valves are available in the aortic sizes indicated in Table 1. Epic Supra valves are designed for supra-annular implantation of both the valve and the sewing cuff. The sewing cuff is the only difference between the Epic valve and the Epic Supra valve.

The Epic and Epic Supra valves are treated with the Linx™ anticalcification process.

Table 1: Model Number Descriptions and Reference Dimensions

<u>Model Number</u>	<u>Tissue Annulus Diameter (mm)</u>	<u>Aortic/Ventricular Protrusion (mm)</u>	<u>Total Height (mm)</u>	<u>Cuff Outer Diameter (mm)</u>
<i>Aortic Heart Valves, Epic</i>				
E100-21A-00	21	9	14	25
E100-23A-00	23	9	15	27
E100-25A-00	25	10	16	29
E100-27A-00	27	11	17	31
E100-29A-00	29	12	19	33
<i>Aortic Heart Valves, Epic Supra</i>				
ESP100-19-00	19	11	14	25

ESP100-21-00	21	11	15	28
ESP100-23-00	23	13	16	29
ESP100-25-00	25	13	17	31
ESP100-27-00	27	14	19	33
<i>Mitral Heart Valves, Epic</i>				
E100-27M-00	27	9	17	35
E100-29M-00	29	10	19	37
E100-31M-00	31	10	20	39
E100-33M-00	33	11	20	41

INDICATIONS FOR USE

The Epic valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. It may also be used as a replacement for a previously implanted aortic and/or mitral prosthetic heart valve.

The Epic Supra valve is indicated as a replacement for a diseased, damaged, or malfunctioning native aortic heart valve. It may also be used as a replacement for a previously implanted aortic prosthetic heart valve.

CONTRAINDICATIONS

None known.

WARNINGS AND PRECAUTIONS

Warnings

- Valve size selection is based on the size of the recipient annulus, and for supra-annular aortic placement, the anatomy of the sinotubular space. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the St. Jude Medical Bioprosthetic Heart Valve Sizer Set Model B1000 with the Epic and Epic Supra valves.
- Accelerated deterioration due to calcific degeneration of the Epic and Epic Supra valve may occur in:
 - children, adolescents, or young adults;
 - patients with altered calcium metabolism (e.g., patients with hyperparathyroidism or chronic renal failure); or
 - individuals requiring hemodialysis.
- For single use only.
- **Do not** resterilize the valve by any method.
- Passage of a catheter or transvenous pacing lead through any bioprosthesis may damage the valve and is therefore not recommended.

Do not use if:

- the valve has been dropped, damaged, or mishandled in any way, or if there is any sign of deterioration;
- the expiration date has elapsed;
- the tamper-evident container seal is damaged, broken, or missing, or if fluid is leaking from the packaging; or
- the storage solution does not completely cover the valve.

Precautions

- The safety and effectiveness of the Epic and Epic Supra valves has not been established for the following specific populations:
 - patients who are pregnant
 - nursing mothers
 - patients with chronic renal failure
 - patients with aneurysmal aortic degenerative conditions (e.g., cystic medial necrosis, Marfan's syndrome)
 - patients with chronic endocarditis
 - patients requiring pulmonic or tricuspid valve replacement
 - children, adolescents, or young adults
- Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. **Do not** use cracked, deformed, or damaged sizer set components.
- **Do not** pass the flanged portion of the valve replica sizing tool through the annulus.
- **Do not** place the non-sterile exterior of the valve container in the sterile field.
- **Do not** expose the valve to solutions other than the formaldehyde valve storage solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline solution used to irrigate the valve.
- **Do not** add antibiotics to either the formaldehyde valve storage solution or the rinse solution.
- **Do not** apply antibiotics to the valve.
- **Do not** allow the valve tissue to dry. Place the valve in sterile isotonic saline rinse solution immediately upon removal from the valve storage solution. Once removed from this solution, the valve should be periodically irrigated during implantation.
- **Do not** use the valve if shipping temperature indicators on the product carton have turned red, or if the valve has been improperly stored in temperature conditions outside of the 5 °C to 25 °C range.
- **Do not** implant the valve without thoroughly rinsing as directed.
- **Do not** lacerate the valve tissue. If a valve is damaged, the valve must be explanted and replaced.
- **Do not** attempt to repair a valve. Damaged valves must not be used.
- **Do not** use cutting edge needles, unprotected forceps, or sharp instruments as they may cause structural damage to the valve.
- Never handle the leaflet tissue.
- Position the mitral valve in a manner to avoid commissure obstruction of the left ventricular outflow tract, and minimize any potential of commissure contact with the ventricular wall.
- Position the aortic valve so that the stent posts do not obstruct the coronary ostia.
- Avoid prolonged contact with the formaldehyde storage solution. Immediately after contact, thoroughly flush any skin exposed to the solution with water. In case of contact with eyes, flush with water and seek appropriate medical care.

MRI Safety Information

Non-clinical testing has demonstrated that the Epic and Epic Supra valves are MR Conditional. They can be scanned safely under the following conditions:

- static magnetic field of 3-Tesla or less
- spatial gradient of 525 Gauss/cm or less
- maximum whole-body-averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes of scanning

In non-clinical testing, the Epic and Epic Supra valves produced a temperature rise of less than or equal to 0.5 °C at a maximum whole body averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes of MR scanning in a 3-Tesla Signa model (GE) MR scanner. MR image quality may be compromised if the area of interest is the exact same area or relatively close to the position of the device.

ADVERSE EVENTS

The clinical investigation of the Epic valve supports the safety and effectiveness of the Epic valve and the Epic Supra valve. Between January 2003 and March 2006, seven-hundred and sixty-two (762) subjects were implanted with 791 Epic Valve(s) at 19 investigational sites in the United States (U.S.), and three sites in Canada. Five-hundred and fifty-seven (557) subjects received isolated aortic replacement, 176 received isolated mitral replacement, and 29 received replacement of both the aortic and mitral valves. The cumulative follow-up for all subjects was 773.51 patient-years with a mean follow-up of 1.02 patient-years (s.d. = 0.71 patient-years, range 0 – 3.10 patient-years).

Potential Adverse Events

Adverse events potentially associated with the use of bioprosthetic heart valves (in alphabetical order) include:

- angina
- cardiac arrhythmias
- endocarditis
- heart failure
- hemolysis
- hemolytic anemia
- hemorrhage, anticoagulant/antiplatelet-related
- leak, transvalvular or paravalvular
- myocardial infarction
- nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other)
- prosthesis regurgitation
- stroke
- structural deterioration (calcification, leaflet tear, or other)
- thromboembolism
- valve thrombosis

It is possible that these complications could lead to:

- reoperation
- explantation
- permanent disability
- death

CLINICAL STUDIES

The clinical investigation of the Epic valve supports the safety and effectiveness of the Epic valve and the Epic Supra valve.

This Epic valve clinical investigation was a multi-center, multi-country, prospective, non-randomized, observational study, without concurrent or matched controls, conducted under a common protocol. Bayesian methods were used for the design and analysis of this study. This statistical methodology provides a framework for "borrowing" historical data from the SJM Biocor™ Valve PMA data.

Seven-hundred and sixty-two (762) subjects were implanted with 791 Epic Valve(s) between January 2003 and March 2006 at 19 investigational sites in the United States (U.S.), and three sites in Canada. Five-hundred and fifty-seven (557) subjects received isolated aortic replacement, 176 received isolated mitral replacement, and 29 received replacement of both the aortic and mitral valves. Demographic and baseline data were collected preoperatively. Postoperative data, including blood and echocardiography data were collected at discharge, 6 months, one year, and annually thereafter. All echos were sent to the Echo Core

Lab for interpretation. Adverse event data (**Table 2**) was collected at the time of occurrence or site notification using definitions from Edmunds et al., 1996¹.

The mean age at implant for all subjects was 73.9 years (s.d. = 9.2 years, range 24-93 years). Preoperatively, 57.4 % of all subjects were NYHA classification III/IV. The cumulative follow-up for all subjects was 773.51 patient-years with a mean follow-up of 1.02 years (s.d. = 0.71 years, range 0 – 3.10 years).

Follow-Up

Table 3 presents the number of patients implanted, cumulative follow-up, and late follow-up for each implant position.

Preoperative Patient Demographics

Table 4 presents the preoperative patient demographics.

Effectiveness Outcomes

Quantitative data were collected throughout the study (i.e., NYHA functional classification, echo parameters). **Table 5** presents patient NYHA classification at one year follow-up. **Tables 6** and **7** present the hemodynamic follow-up results for the Epic aortic and mitral valve replacements.

INDIVIDUALIZATION OF TREATMENT

Anticoagulant and/or Antiplatelet Therapy

Long-term, low-dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism.

PATIENT COUNSELING INFORMATION

Long-term, low-dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism.

Patients with bioprostheses who undergo dental or other procedures that are potentially bacteremic should receive endocarditis prophylactic antibiotic therapy.

St. Jude Medical publishes a patient brochure. Copies of this booklet are available through your SJM sales representative.

¹ Edmunds LH, Clark RE, Cohn LH, Grunkemeier GL, Miller CM, Weisel RD. Guidelines for Reporting Morbidity and Mortality after Cardiac Valvular Operations. Ann Thorac Surg 1996;62:932-5.

PACKAGING AND STORAGE

As delivered, the valve is attached to a valve holder by three retaining sutures. A flexible plastic support surrounds the valve. The valve holder and support facilitate handling and manipulation of the valve during removal from the container, rinsing, and implantation.

The valve is packaged in a formaldehyde storage solution.

Store the valve in the upright position.

The valve should be stored in temperatures from 5 °C to 25 °C (41 °F to 77 °F). Do not store the valve where significant temperature fluctuations may occur.

CAUTION: Do not implant the valve without thoroughly rinsing as directed.

CAUTION: Do not use the valve if shipping temperature indicators on the product carton have turned red, or if the valve has been improperly stored in temperature conditions outside the 5 °C to 25 °C (41 °F to 77 °F) range.

DIRECTIONS FOR USE

Pre-Implant Handling

The Epic and the Epic Supra valves are supplied in a storage container with a screw-cap closure and tamper-evident seal. The contents of the container are sterile, and must be handled aseptically to prevent contamination.

Warnings

- **Do not** use the valve if the expiration date has elapsed.
- **Do not** use the valve if fluid is leaking from the packaging.
- **Do not** resterilize the valve by any method.

Removing the Valve From the Outer Packaging

Precautions

- **Do not** place the non-sterile exterior of the valve container in the sterile field.
 - **Do not** expose the valve to solutions other than the formaldehyde valve storage solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline solution used to irrigate the valve.
 - **Do not** add antibiotics to either the formaldehyde valve storage solution or the rinse solution.
 - **Do not** apply antibiotics to the valve.
1. After sizing, choose a valve of the appropriate size.
 2. Once the valve container has been removed from the outer packaging, examine the container for evidence of damage.

WARNING: The valve must not be implanted if the tamper-evident container seal is damaged, broken, or missing; or if fluid is leaking from the packaging.

WARNING: The valve must not be implanted if the storage solution does not completely cover the valve.

3. Verify the valve size and expiration date on the label.
4. To remove the valve from the container, break the seal and remove the screw-top closure.

CAUTION: Avoid prolonged contact with the formaldehyde storage solution. Immediately after contact, thoroughly flush any skin exposed to the solution with water. In case of contact with eyes, flush with water and seek appropriate medical care.

5. Complete the medical device registration form and return it to St. Jude Medical. Place one of the pull-off labels with the designated model and serial number in the patient's chart.

Removing the Valve From the Storage Container

1. Select the valve holder handle model B1000-H.

2. With the circulating nurse holding the container, press the valve holder handle into the valve holder as shown in **Figure 3**, and remove the valve from the container.

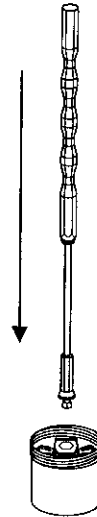


Figure 3: Press the valve holder handle into the valve holder.

CAUTION: Do not handle the valve with unprotected forceps or sharp instruments. Never handle the leaflet tissue.

3. Inspect the valve for damage.

WARNING: Do not implant the valve if it has been dropped, damaged, or mishandled in any way, or if there is any sign of deterioration.

Rinse Procedure

CAUTION: Do not implant the valve without thoroughly rinsing as directed.

1. Within the sterile field, prepare two sterile basins with a minimum of 500 ml of sterile isotonic saline solution in each basin.
2. Holding the valve by the handle, **fully immerse** the valve support, the valve, the valve holder, and the portion of the holder handle that was submerged in the valve storage solution, in the sterile isotonic saline solution in the first basin.
3. Continually rinse the valve for 10 seconds, using a gentle back-and-forth motion.
4. Repeat steps two and three in the second basin.
5. After rinsing, leave the valve immersed in the basin until required by the surgeon for implantation.
6. Prior to implantation, remove the valve support by depressing the three tabs below the level of the valve support ring, as indicated in **Figure 4**.

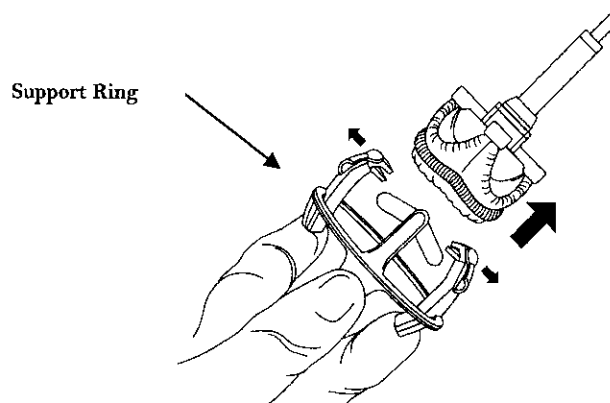


Figure 4: To release the valve support from the valve cuff, depress the three tabs at the base of the valve support, below the support ring.

CAUTION: Do not allow the valve tissue to dry. Place the valve in sterile isotonic saline rinse solution immediately upon removal from the valve storage solution.

Sizing Epic Standard Aortic Valves

Epic standard aortic valves are designed for intra-annular stent placement and supra-annular cuff placement.

To determine the correct standard aortic valve size, use the Model B1000 aortic sizers. The Model B1000 aortic sizer is a double-ended tool, with a supra valve replica end and an annular sizing end (**Figure 5**).

Note: Use only the annular sizing end of the B1000 sizer to size standard aortic valves.

Identify the sizer that fits snugly in the annulus and select the corresponding valve size.

WARNING: Standard aortic valve size selection is based on the size of the recipient annulus. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the St. Jude Medical Model B1000 sizers to size Epic standard aortic valves.

CAUTION: Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, deformed, or damaged sizer set components.

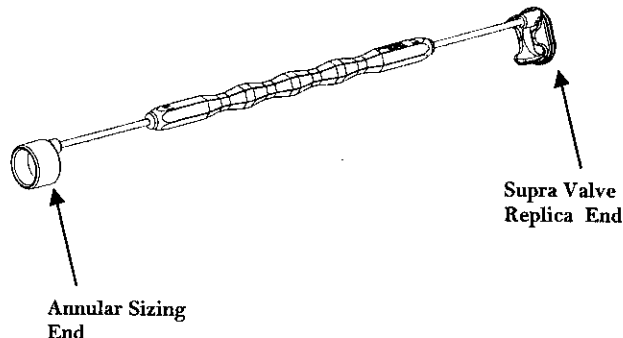


Figure 5: Aortic Sizer

Sizing Epic Supra Aortic Valves

Epic Supra valves are designed for supra-annular aortic placement.

To determine the correct supra aortic valve size, use the Model B1000 aortic sizers. The aortic sizer is a double-ended tool, with a supra valve replica end and an annular sizing end. Use the annular sizing end to determine the size of the annulus. Insert the corresponding supra valve replica end in the supra-annular space to confirm placement and fit of the valve (**Figure 6**).

WARNING: Supra-annular aortic valve size selection is based on the size of the recipient annulus and the anatomy of the sinotubular space. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only St. Jude Medical Sizer Set Model B1000 to size Epic Supra valves.

CAUTION: Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, deformed, or damaged sizer set components.

CAUTION: Do not pass the flanged portion of the supra valve replica sizing tool through the annulus.

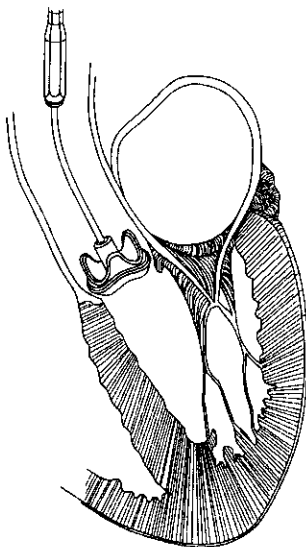


Figure 6: Place the supra valve replica end in the supra-annular space to confirm placement and fit of the Epic Supra valve.

Sizing Epic Mitral Valves

Epic mitral valves are designed for intra-annular stent placement and supra-annular cuff placement.

To determine the correct standard mitral valve size, use the Model B1000 mitral sizers (Figure 7). Identify the sizer that fits snugly in the annulus and select the corresponding valve size.

WARNING: Mitral valve size selection is based on the size of the recipient annulus. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only St. Jude Medical Sizer Set Model B1000 to size Epic mitral valves.

CAUTION: Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, deformed, or damaged sizer set components.



Figure 7: Mitral Sizer

Surgical Guidelines

The actual choice of surgical technique, modified in accordance with the instructions described herein, is left to the discretion of the individual surgeon.

When implanting supra-annular valves, non-everting mattress sutures are recommended.

Avoid any contact between the implantation sutures and the leaflets.

Precautions

- **Do not** allow the valve tissue to dry. Place the valve in isotonic sterile saline rinse solution immediately upon removal from the valve storage solution. Once removed from this solution, the valve should be periodically irrigated during implantation.
- **Do not** use cutting edge needles, unprotected forceps, or sharp instruments as they may cause structural damage to the bioprosthesis.
- Never handle the leaflet tissue.
- **Do not** lacerate the valve tissue. If a valve is damaged, the valve must be explanted and replaced.
- **Do not** attempt to repair a valve. Damaged valves must not be used.

Aortic Valve Implantation

The Epic aortic valve is designed to allow intra-annular placement of the inflow edge of the valve with supra-annular placement of the sewing cuff. The Epic Supra valve is designed for supra-annular implantation of both the valve and the sewing cuff.

1. After sizing, choose a valve of the appropriate size.

CAUTION: Position the valve so that the stent posts do not obstruct the coronary ostia.

2. To facilitate implantation, the valve holder handle may be removed from the valve holder by depressing the release button on the valve holder (Figure 8).
3. To remove the valve holder from the valve, cut the three retaining sutures as shown in Figure 9, and pull the valve holder away from the valve. Examine the valve to ensure that there are no holder suture remnants.

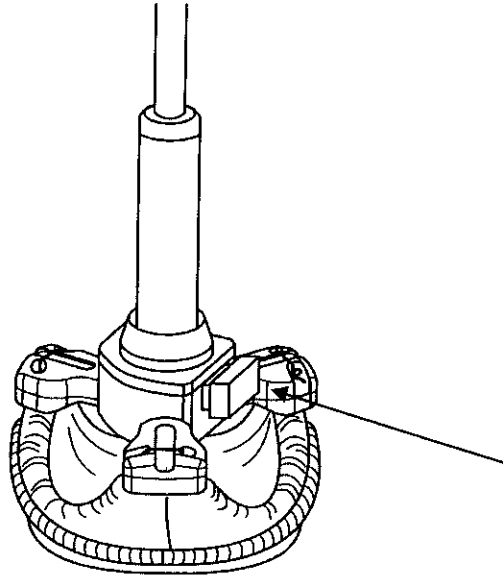


Figure 8: Release the valve holder handle by depressing the button.

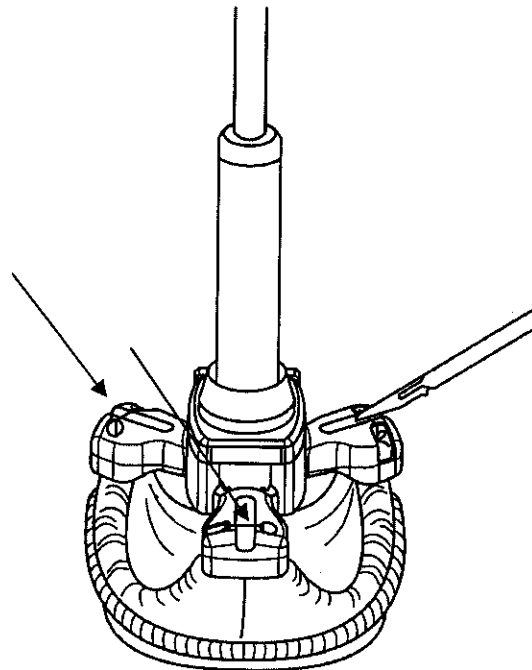


Figure 9: Cut three sutures to remove aortic holder.

Mitral Valve Implantation

1. After sizing, choose a valve of the appropriate size.

CAUTION: Position the mitral valve in a manner to avoid commissure obstruction of the left ventricular outflow tract, and minimize any potential of commissure contact with the ventricular wall.

2. To facilitate insertion of the mitral valve into the annulus, the mitral valve stent posts may be temporarily deflected inward during implantation. To deflect the valve stent posts inward, rotate the valve holder

handle in the clockwise direction (**Figure 10**) while securing the valve holder. The valve stent posts will remain deflected until the valve retaining sutures are cut. To facilitate implantation, the valve holder handle may be removed from the valve holder by depressing the release button on the valve holder.

NOTE: Take care to avoid looping or entangling sutures around the commissural posts, as this may result in a compromise of leaflet function.

3. To remove the valve holder from the valve, cut the three retaining sutures as shown in **Figure 11**, and pull the valve holder away from the valve. Examine the valve to ensure that there are no holder suture remnants.

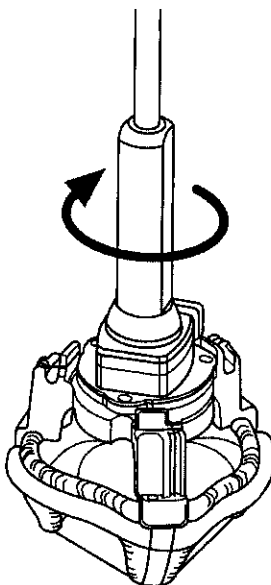


Figure 10: Rotate the valve holder handle to deflect the mitral stent posts inward.

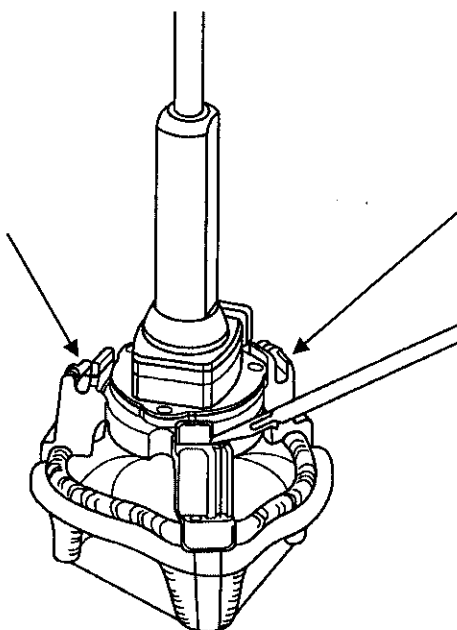


Figure 11: Cut three sutures to remove mitral holder.

INTRA-OPERATIVE ASSESSMENT

The suggested method for assessing competence of the Epic and the Epic Supra valve is with intra-operative Doppler echocardiography.

PATIENT REGISTRATION

A medical device registration form is included with each device. After implantation, please complete all requested information, and return the original form to the address indicated on the medical device registration form. Tracking by manufacturers is mandatory within the United States and Canada. For countries outside of the United States and Canada, please disregard any request for patient information if this contradicts your local legal or regulatory requirements regarding patient privacy.

LIMITED WARRANTY

St. Jude Medical (SJM) warrants that reasonable care has been used in the manufacturing of this device. THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, since handling, storage, cleaning, and sterilization of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond SJM's control directly affect this device and the results obtained from its use. SJM SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE directly or indirectly arising from the use of this device other than the replacement of all or part of it. SJM neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Some states in the United States do not allow limitations on how long an implied warranty lasts, so the above limitations may not apply to you. This limited warranty gives you specific legal rights, and you may have other rights which vary from jurisdiction to jurisdiction.

Descriptions of specifications, appearing in SJM literature, are meant solely to generally describe the device at the time of manufacture and do not constitute any express warranties.

TABLES

Table 2: Observed Adverse Event Rates

All subjects entered into study: N=762, cumulative follow-up=717.4 late patient-years

Adverse Event	Early Events ¹ n (%)	Late Events ² n (% / pt-yr)	Bayesian Posterior mean rate ³	Freedom From Event 1 Year % [95% CI]
Hemolysis	2 (0.3)	1 (0.1)	0.104	99.6% [98.6%, 99.9%]
Structural Deterioration	0 (0.0)	2 (0.3)	0.324	100.0% [100.0%, 100.0%]
Paravalvular Leak	2 (0.3)	11 (1.5)	1.363	98.2% [96.7%, 99.0%]
Embolism	20 (2.6)	18 (2.5)	2.136	94.8% [92.8%, 96.3%]
Valve Thrombosis	1 (0.1)	0 (0.0)	0.014	99.8% [98.9%, 100.0%]
Major Bleeding Events – Anticoagulant and/or Antiplatelet Related Hemorrhage	38 (5.0)	13 (1.8)	1.357	93.2% [91.0%, 94.9%]
• Anticoagulant Related Hemorrhage ⁴	27(3.5)	7 (0.98)	0.88	95.2% [93.2%, 96.6%]
Endocarditis	1 (0.1)	9 (1.3)	0.845	98.5% [97.1%, 99.2%]
Reoperation	1 (0.1)	11 (1.5)	1.456	98.3% [96.8%, 99.1%]
Mortality - Valve Related	2 (0.3)	5 (0.7)	0.804	99.2% [98.1%, 99.7%]

1. Early events are those occurring on or before 30 days post-implant. The early adverse event rate (%) is calculated as the number of early adverse events divided by the total number of subjects implanted, times 100.

2. Late events are those occurring 31 days post-implant or thereafter.

3. Bayesian posterior mean are the event rates modeled from a Bayesian hierarchical model.

4. Excludes subjects receiving only antiplatelet therapy.

Table 3. Patient Numbers, and Cumulative and Late Patient follow-up

All subjects entered into study, N=762

Mean, SD, Min, and Max are represented in "Patient-years"

Implant Position	Number of Subjects	Total Patient- years	Mean	SD	Minimum	Maximum
Cumulative Patient-years						
Isolated Aortic	557	582.13	1.05	0.70	0.00	3.08
Isolated Mitral	176	168.96	0.96	0.73	0.00	3.10
Double	29	22.43	0.77	0.66	0.02	2.01
All Implants	762	773.51	1.02	0.71	0.00	3.10
Late Patient-years*						
Isolated Aortic	474	540.93	1.14	0.61	0.00	3.00
Isolated Mitral	147	156.12	1.06	0.65	0.02	3.01
Double	23	20.34	0.88	0.60	0.02	1.93
All Implants	644	717.40	1.11	0.62	0.00	3.01

* Late patient-years at risk are determined from 31 days post-implant to the censoring event.

Table 4. Preoperative Patient Demographics
All subjects entered into study: N=762

Variable	Isolated Aortic (N=557)	Isolated Mitral (N=176)	Double (N= 29)	All (N=762)
Age	74.4 ± 9.3 (24, 93)	72.1 ± 8.9 (44, 91)	75.9 ± 8.3 (55, 92)	73.9 ± 9.2 (24, 93)
Gender (Male)	61.0%	44.3%	34.5%	56.2%
Preoperative NYHA				
I	9.2%	8.0%	0.0%	8.5%
II	34.6%	30.1%	34.5%	33.6%
III	43.1%	43.2%	34.5%	42.8%
IV	12.6%	18.2%	31.0%	14.6%
Unknown	0.5%	0.6%	0.0%	0.5%

Table 5: Effectiveness Outcomes, NYHA Functional Classification: 1 year Follow-up*

Subjects with both preoperative and 1 year NYHA measurements, N=460; n₁=number per subgroup

NYHA Class	Isolated Aortic n=353				Isolated Mitral n=93				Double n=14			
	Preoperative		1 Year		Preoperative		1 Year		Preoperative		1 Year	
	n ₁	% (n ₁ /n)	n ₁	% (n ₁ /n)	n ₁	% (n ₁ /n)	n ₁	% (n ₁ /n)	n ₁	% (n ₁ /n)	n ₁	% (n ₁ /n)
I	35	9.9	244	69.1	6	6.5	66	71.0	0	0	12	85.7
II	131	37.4	98	27.8	30	32.3	22	23.7	6	42.9	1	7.1
III	146	41.1	11	3.1	40	43.0	5	5.4	4	28.6	1	7.1
IV	39	11.0	0	0	17	18.3	0	0	4	28.6	0	0
All	353	100.0	353	100.0	93	100.0	93	100.0	14	100.0	14	100.0

*Subjects with both preoperative and one year NYHA measurements available are included in this table.

Table 6: Effectiveness Outcomes at One Year Follow-up Visit, Hemodynamic Results - All Aortic Valves
All aortic subjects entered into study: N=586

Hemodynamic Parameter	21mm	23mm	25mm	27mm	29mm*
Mean Gradient	n= 49	n=120	n=121	n= 36	n= 10
~ Mean \pm SD	19.1 \pm 8.2	13.9 \pm 6.0	12.1 \pm 5.1	11.4 \pm 4.1	7.5 \pm 3.3
~ Min, Max	3.1, 43.5	1.7, 35.0	3.7, 34.3	6.5, 26.3	2.7, 12.7
EOA	n= 46	n=118	n=121	n= 35	n= 10
~ Mean \pm SD	1.0 \pm 0.3	1.4 \pm 0.5	1.5 \pm 0.5	1.6 \pm 0.4	2.4 \pm 1.1
~ Min, Max	0.5, 2.3	0.5, 3.5	0.2, 3.3	0.8, 2.7	1.2, 4.6
Regurgitation	n= 56	n=130	n=128	n= 38	n= 10
~ None	47 (84%)	103 (79%)	92 (72%)	28 (74%)	9 (90%)
~ Trivial	7 (13%)	21 (16%)	29 (23%)	9 (24%)	1 (10%)
~ Mild	2 (4%)	6 (5%)	6 (5%)	1 (3%)	0 (0%)
~ Moderate	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)
~ Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
~ Unknown	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Includes 2 subjects at greater than one year visit

n= number of subjects evaluated

Mean Gradient = pressure drop measured across the valve recorded in mmHg

EOA= calculated effective orifice area measured in cm²

Regurgitation presented as Count (Percentage)

Table 7: Effectiveness Outcomes at One Year Follow-up Visit, Hemodynamic Results - All Mitral Valves
All mitral subjects entered into study: N=205

Hemodynamic Parameter	27mm*	29mm	31mm	33mm*
Mean Gradient	n= 30	n= 41	n= 26	n= 24
~ Mean \pm SD	6.1 \pm 2.9	5.5 \pm 1.7	4.8 \pm 1.4	4.1 \pm 1.6
~ Min, Max	2.7, 14.0	2.9, 10.0	2.6, 8.3	1.5, 7.9
EOA	n= 16	n= 26	n= 15	n= 22
~ Mean \pm SD	1.4 \pm 0.7	1.5 \pm 0.5	1.6 \pm 0.3	1.5 \pm 0.3
~ Min, Max	0.6, 3.1	0.6, 2.8	1.1, 2.4	1.1, 2.2
Regurgitation	n= 30	n= 45	n= 28	n= 25
~ None	30 (100%)	41 (91%)	23 (82%)	23 (92%)
~ Trivial	0 (0%)	1 (2%)	0 (0%)	1 (4%)
~ Mild	0 (0%)	3 (7%)	5 (18%)	0 (0%)
~ Moderate	0 (0%)	0 (0%)	0 (0%)	1 (4%)
~ Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)
~ Unknown	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Includes 4 (27mm) and 6 (33mm) subjects at greater than one year visit.

n= number of subjects evaluated

Mean Gradient = pressure drop measured across the valve recorded in mmHg

EOA= calculated effective orifice area measured in cm²

Regurgitation presented as Count (Percentage)

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